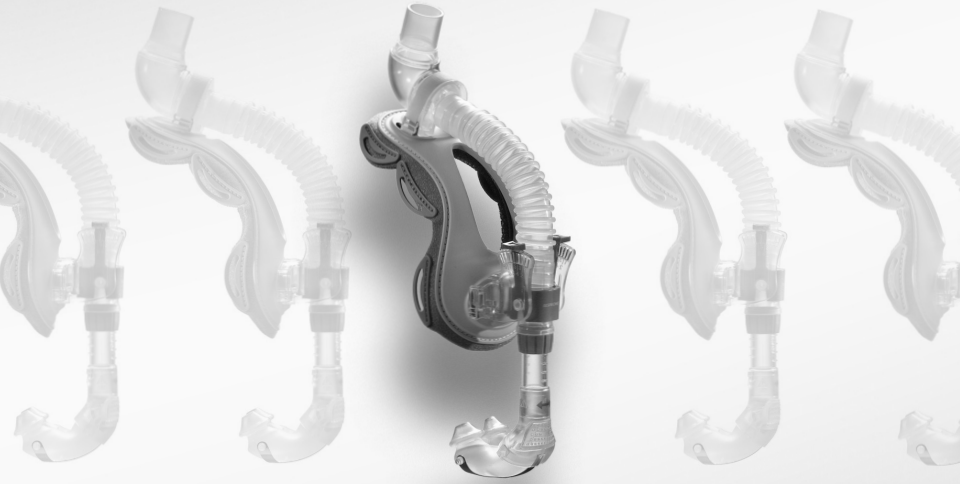

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1067728
JDH 03/30/2010
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RESPIRONICS

ComfortLite 2

INSTRUCTIONS FOR USE

ComfortLite 2 Nasal Mask

Table of Contents

3 Package Contents
4 Intended Use
5 Warnings
7 Symbols
8 Before Use
8 Cleaning Instructions
9 System One Resistance Control
10 Sizing & Attaching the Cushion
16 Achieving the Right Fit
19 Removing the the Mask from the Headgear
20 Specifications
21 Disposal
22 Limited Warranty
24 Reorder Information

INSTRUCTIONS FOR USE

ComfortLite 2 Nasal Mask

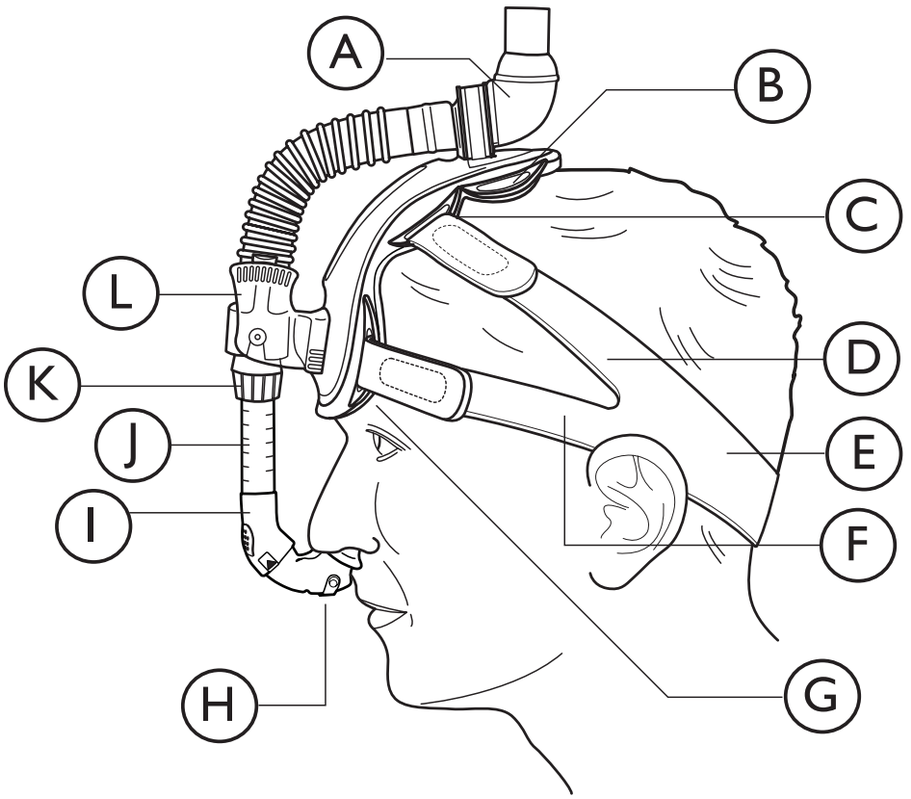


Figure 1

A = Crown Swivel Connector
B = Top Connection Point
C = Middle Connection Point
D = Upper Strap
E = Back Strap
F = Lower Strap (behind or over ears)
G = Front Connection Point
H = Metal Support Band (Pillows or Direct Seal)
I = Cradle
J = Vertical Tube
K = Vertical Tube Adjustment
L= Angular Adjustment

Package Contents

- ComfortLite 2 nasal interface assembly
  - Headgear
  - Cushions
- Instructions for use
- Quick fit tips

NOTE:
Additional accessories and replacement parts are available. Please see the reorder box located in the back of these instructions.

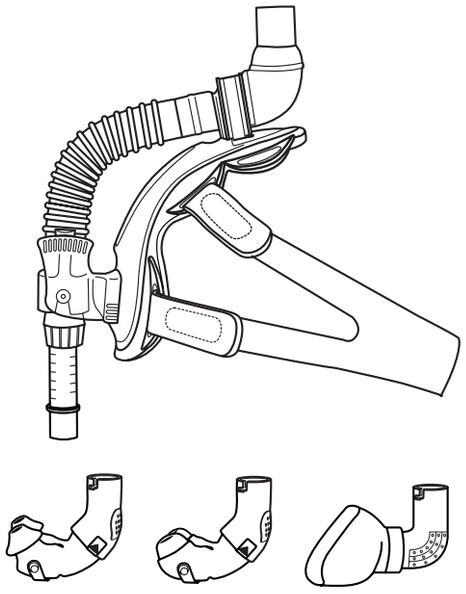


Figure 2

Nasal interface assembly, headgear & cushions

Intended Use

The ComfortLite 2 Nasal Mask is intended to provide an interface for application of CPAP or bi-level therapy to patients. The mask is for single patient use in the home or multi-patient use in the hospital/institutional environment. The mask is to be used on patients (>66lbs/30kg) for whom CPAP or bi-level therapy has been prescribed.

Important Notes:

- An exhalation port is built into the ComfortLite 2 Nasal Mask so a separate exhalation port is not required
- Device pressures should be verified when used by other vendor's auto-titrating devices. ComfortLite 2 has been validated to work with all Respironics CPAP and bi-level therapy devices.

Caution: U.S. federal law restricts this device to sale by or on the order of a physician.

⚠ Warnings:

- This mask is not suitable for providing life support ventilation.
- This mask is designed for use with CPAP or bi-level systems recommended by your health care professional or respiratory therapist. Do not wear this mask unless the CPAP or bi-level system is turned on and operating properly. **Do not block or try to seal the exhalation port. Explanation of the Warning:** CPAP systems are intended to be used with special masks with connectors which have vent holes to allow continuous flow of air out of the mask. When the CPAP machine is turned on and functioning properly, new air from the CPAP machine flushes the exhaled air out through the attached mask exhalation port. However, when the CPAP machine is not operating, enough fresh air will not be provided through the mask, and exhaled air may be rebreathed. This warning applies to most models of CPAP systems. Rebreathing of exhaled air for longer than several minutes can, in some circumstances, lead to suffocation.

⚠ *Warning*

A warning indicates the possibility of injury to the user or operator.

⚠ *Caution*

A caution indicates the possibility of damage to the device.

Note

A note places an emphasis on an operating characteristic.

- If oxygen is used with the device, the oxygen flow must be turned off when the device is not operating. **Explanation of the Warning:** When the device is not in operation, and the oxygen flow is left on, oxygen delivered into the ventilator tubing may accumulate within the device enclosure. Oxygen accumulated in the device enclosure will create a risk of fire.
- Oxygen supports combustion. Oxygen should not be used while smoking or in the presence of an open flame.
- At a fixed flow rate of supplemental oxygen flow, the inhaled oxygen concentration will vary, depending on the pressure settings, patient breathing pattern, mask selection, and the leak rate. This warning applies to most types of CPAP and bi-level machines.
- Some users may experience skin redness, irritation, or discomfort. If this happens, discontinue use and contact your healthcare professional.
- At low CPAP or EPAP pressures, the flow through the exhalation port may be inadequate to clear all exhaled gas from the tubing. Some rebreathing may occur.
- If an additional exhalation device is added to the patient circuit, you may need to adjust the pressure level to compensate for the additional leak of the exhalation device.
- Hand wash prior to first use. Inspect the mask for damage or wear (cracking, crazing, tears, etc). Discard and replace any components as necessary.

Symbols

This table defines the symbols used on the ComfortLite 2 mask and/or in these instructions.

Symbol	Description
	Warning or Caution
X1	System One Control
	Note
	Tip

Before Use

- Hand wash the mask and cushions.
- Read and understand the instructions completely.
- Wash your face.

Cleaning Instructions

Hand wash the mask before first use and daily. The headgear should be hand washed weekly, or as needed. The headgear does not need to be removed for daily cleaning of the mask.

1. Hand wash the mask and headgear in warm water with a mild liquid dish washing detergent.

⚠ **Caution:** Do not use bleach, alcohol, cleaning solutions containing bleach or alcohol, or cleaning solutions containing conditioners or moisturizers.

2. Rinse thoroughly with drinking quality water and air dry out of direct sunlight. Make sure the mask is dry before use. Lay the headgear flat or line dry. Do not place the headgear into the dryer.

3. Inspect all parts for damage or wear; replace any parts that have visibly deteriorated (cracking, crazing, tears, etc). Replace the mask if the cushion becomes hardened.

For **multi-patient use** in the hospital/institutional environment, use the Mask Cleaning and Disinfection Instructions to reprocess the mask between patients. These instructions can be obtained by visiting www.sleepapnea.com or contacting Customer Service at 1-800-345-6443 (USA or Canada) or 1-724-387-4000.

System One Resistance Control

This mask uses the System One Resistance Control setting . This symbol may appear on your therapy device. This symbol represents the level of mask resistance compensation. Match the setting to the mask if appropriate.

Important Notes:

- Verify the System One setting if the mask or mask cushion changes.
- The System One setting is not compatible with masks requiring a separate/ additional exhalation device.

If your provider has locked the resistance compensation setting, you can view the setting but cannot change it, and the screen will display a lock symbol. If your provider has disabled the resistance compensation, you will not see this setting.

Direct Seal		Pillows		Simple	
Size 1	X2	P	X4	P	X1
Size 2	X2	S	X4	S	X1
Size 3	X2	M	X2	M	X1
Size 4	X1	L	X1	L	X1
Size 5	X2				
Size 6	X2				

Sizing & Attaching the Cushion

The ComfortLite 2 may come with an assortment of nasal interface cushions in multiple sizes (Figure 3).

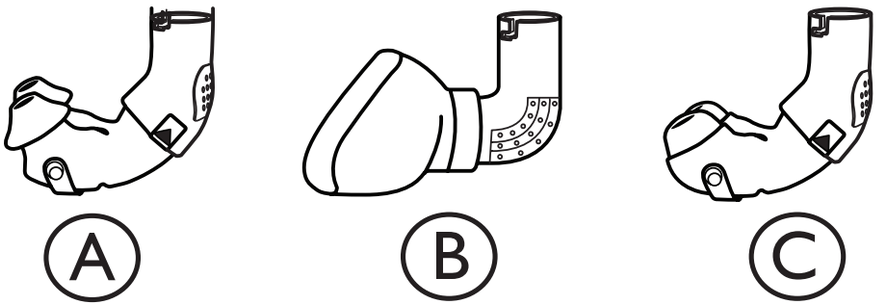


Figure 3

Cushion assortment

A = Pillows Cushion
B = Simple Cushion
C = Direct Seal Cushion

Sizing the Pillows Cushion

To determine the proper size, (Figure 4a) select the Pillows cushion that fills the nostrils without any gaps between the cushion and the nostril walls (Figure 4b & c).

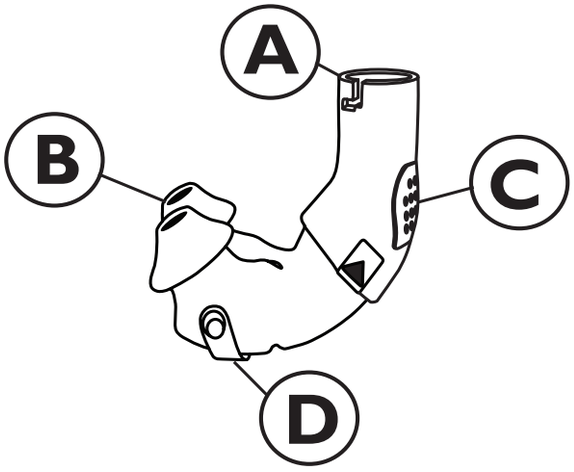


Figure 4a

Pillows cushion
A = Elbow
B = Pillows
C = Exhalation Vent (Do not block)
D = Metal Support

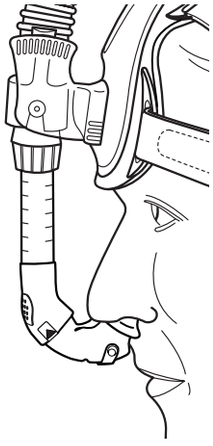


Figure 4b

Correct fit: Pillows inside nostrils

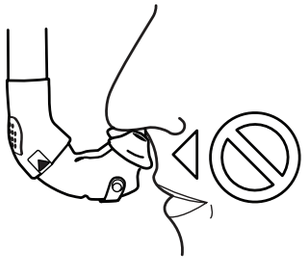


Figure 4c

Incorrect fit: Pillows outside nostrils

Sizing the Simple Cushion

To determine the proper size, start with the smallest Simple cushion in the package. Choose the size that fits over the entire nose without blocking the nostrils (Figure 5b & c).

Slide the smaller opening of the Simple cushion over the ball and socket connector (Figure 5a).

Tip: Position the Simple cushion so the narrower end fits over the bridge of the nose and the wider end is under the nostrils.

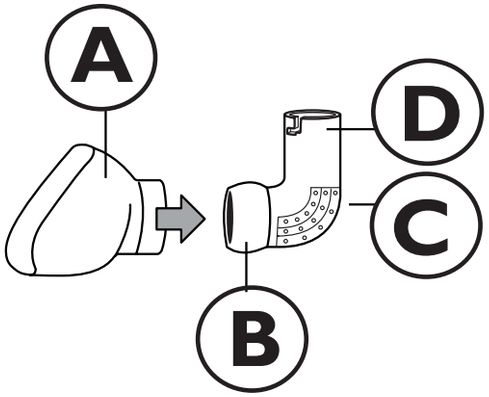
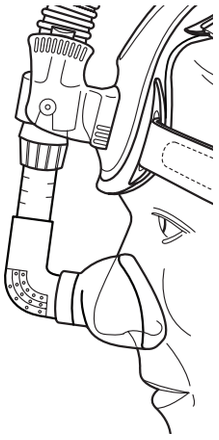


Figure 5a

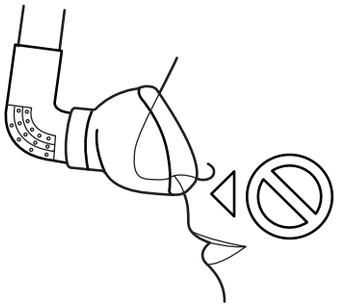
Simple cushion
A = Simple Cushion
B = Ball & Socket Connector
C = Exhalation vent (Do not block)
D = Elbow

Figure 5b



Correct fit - cushion fits over the nose

Figure 5c



Incorrect fit - cushion is placed too high & blocks the nostrils

Comfort Tips

- The Simple cushion should cover but not obstruct the nostrils.
- Pivot the Simple cushion to angle it to your features and to correct leaks.

Sizing the Direct Seal Cushion

To determine the correct size, start with the largest Direct Seal cushion (Figure 6a) in the package. The bulbs of the Direct Seal cushion should rest on the edge of the nostrils, blocking the ends (Figure 6b).

The bulbs should not be inserted into the nostrils (Figure 6c). Therefore, choose a cushion with bulbs larger than your nostrils.

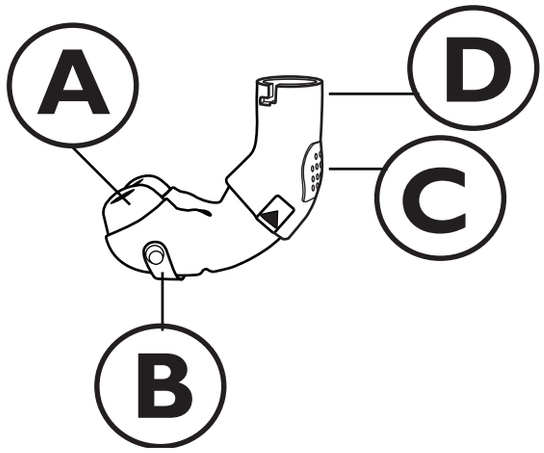


Figure 6a

Direct Seal cushion
A = Direct Seal Bulb
B = Metal Support
C = Exhalation Vent (Do not block)
D = Elbow

Figure 6b

Correct fit - bulbs rest against the nostrils

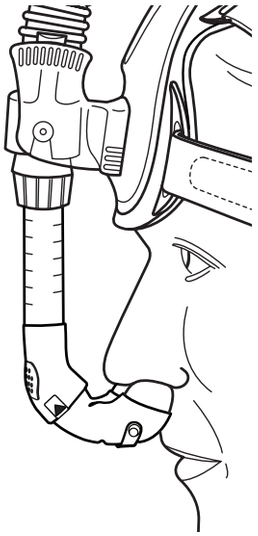
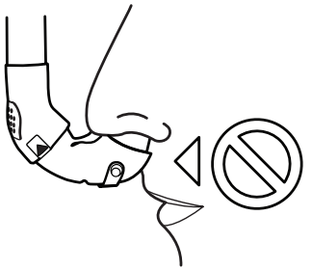


Figure 6c

Incorrect fit - bulbs inside the nostrils

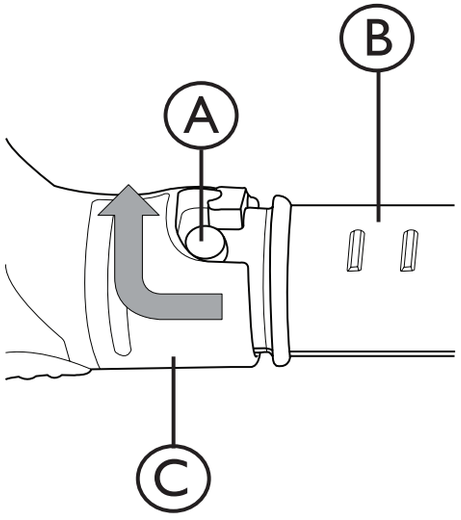


Attaching the Cushion to the Vertical Tube

After you have chosen the proper cushion size and type, align the vertical tube knob with the notch in the rim of the exhalation elbow (Simple cushion) or cradle (Pillows & Direct Seal cushions). Slide the two pieces together and turn the cushion until it clicks into place (Figure 7).

Figure 7

Connecting the cushion to the vertical tube
A = Vertical Tube Knob
B = Vertical Tube
C = Exhalation Elbow



Achieving the Right Fit

The headgear and mask only require a one-time sizing and fitting.

1. Place the headgear against your forehead and pull the straps over your head (Figure 8a).

2. Tighten the lower strap to provide a firm yet comfortable level of stability. The bottom edge of the headgear should rest just above the eyebrows (Figure 8b). The back strap of the headgear should be pulled down toward the back of the neck for maximum support. The straps can be worn behind or over the ears.

3. Adjust the upper strap (if necessary) to improve the fit of the headgear over the top of the head. Do not over-tighten the upper strap. Over-tightening may cause the headgear to rise off of the head.

Note: If the headgear slides on your head or irritates your ears, move the upper strap to a different (upper or middle) connection point.

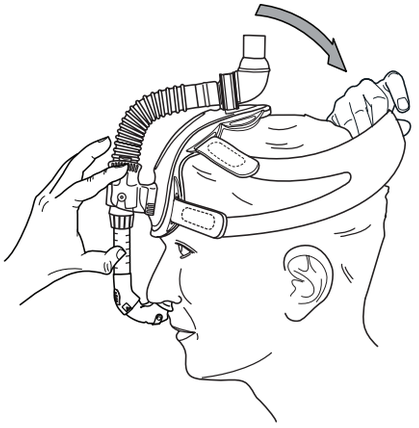


Figure 8a

Pull the straps over your head

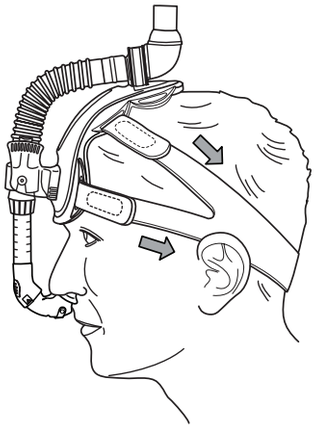


Figure 8b

Proper position of mask on head

To do this, simply unfasten the hook and loop tab, pull the strap through the connection point, and refasten.

Note: Make sure the front of the headgear rests on the brow line.

Comfort Tip: Wear the backstrap under your hair if it is long or silky..

4. To move the cushion closer to or farther from your face, squeeze the tabs on the angular adjustment and pull them outward or inward (Figure 9).

5. To move the cushion up or down, twist the dial on the vertical tube adjustment until the cushion is at the proper height (Figure 10).

6. Bend the metal support band to adjust the Pillows or Direct Seal bulbs to the width of your nostrils (Figure 11).

Note: Do not squeeze the metal band on the Pillows and Direct Seal cushions to move the cushion up or down; always use the angular and/or vertical tube adjustment.

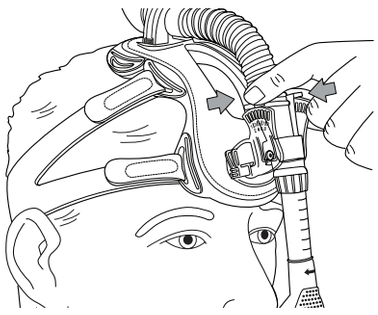


Figure 9

Angular adjustment

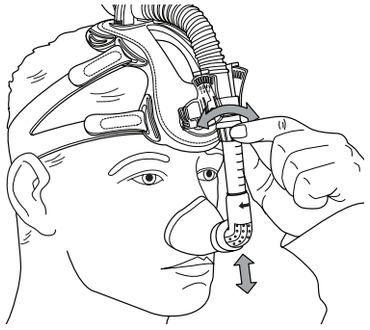


Figure 10

Vertical tube adjustment

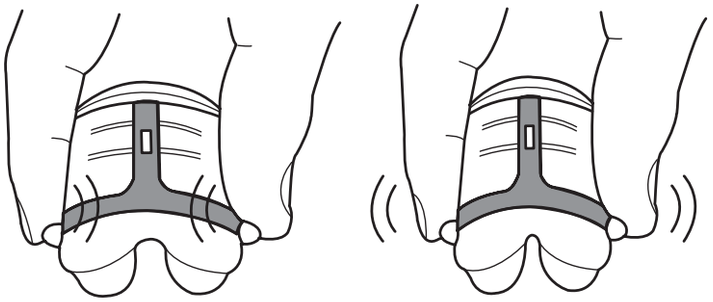


Figure 11

Metal support band adjustment

7. Connect the tubing of the CPAP or bi-level device to the crown swivel connector (Figure 12). Turn on the device and adjust the ComfortLite 2 to correct any leaks.

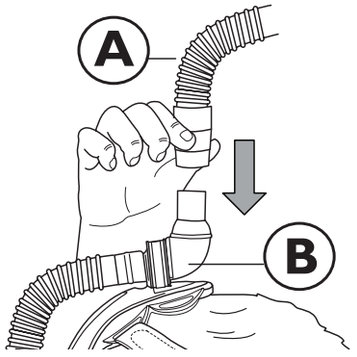


Figure 12

Connect the ComfortLite 2 to the CPAP or bi-level device
A = Device Tubing
B = Crown Swivel Connector

Troubleshooting Leaks

- Try a different size cushion.
- Use the angular and vertical tube adjusters to change the cushion position.
- Tighten or loosen the headgear.
- If you are using the Simple Cushion, verify that it is properly connected to the exhalation elbow.
- Verify that the front of the headgear rests on the brow line (Figure 8b,).

Removing the Mask from the Headgear

First, unfasten the white retaining strap from the crown swivel. Squeeze the clear tabs behind the angular adjuster (Figure 13) and slide them up and off the track. This will completely remove the assembly from the headgear.

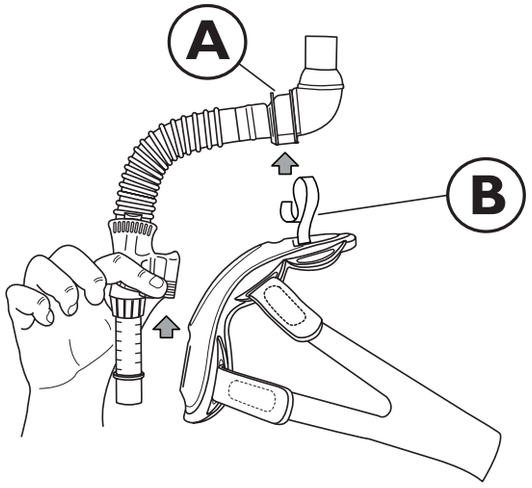


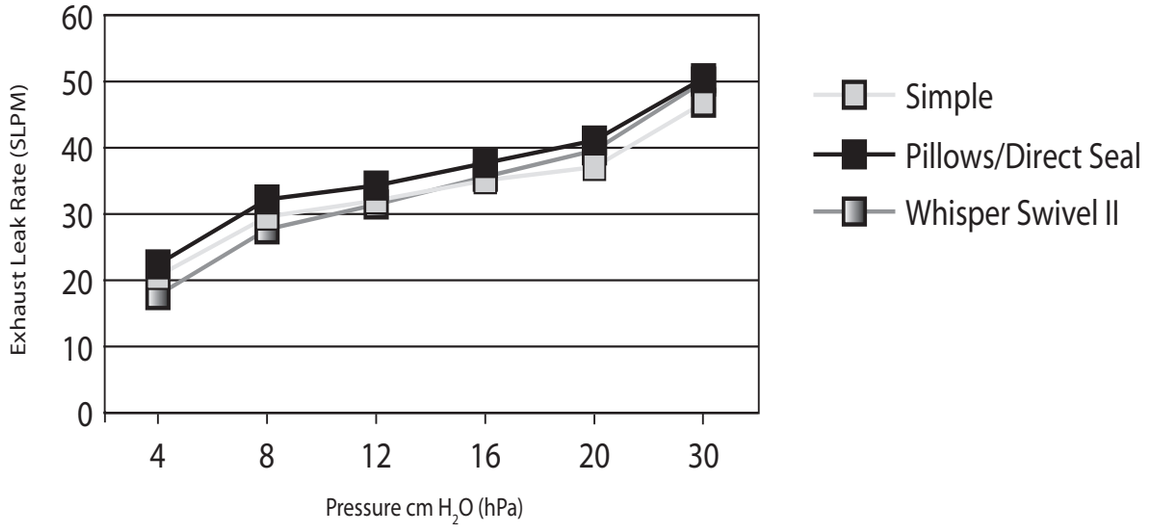
Figure 13

Headgear removal
A = Crown Swivel
B = White Retaining Strap

Specifications

Warning: The technical specifications of the mask are provided for your healthcare professional to determine if it is compatible with your CPAP or bi-level therapy device. If used outside these specifications, or if used with incompatible devices, the mask may be uncomfortable, the seal of the mask may not be effective, optimum therapy may not be achieved, and leak, or variation in the rate of leak, may affect device function.

Intentional Leak



Deadspace Volume

Pillows cushion: 19 - 36cc
Simple cushion: 27 - 65cc
Direct Seal cushion: 14 - 38cc

Storage Conditions

-4° F to 140° F (-20° C to +60° C)
15% to 95% relative humidity, non-condensing

Disposal

Dispose of in accordance with local regulations.

LIMITED WARRANTY

Respironics, Inc. warrants that its mask systems (including mask frame and cushion) (the "Product") shall be free from defects of workmanship and materials for a period of ninety (90) days from the date of purchase (the "Warranty Period").

If the Product fails under normal conditions of use during the Warranty Period and the Product is returned to Respironics within the Warranty Period, Respironics will replace the Product. This warranty is non-transferable and only applies to the original owner of the Product. The foregoing replacement remedy will be the sole remedy for breach of the foregoing warranty. This warranty does not cover damage caused by accident, misuse, abuse, negligence, alteration, failure to use or maintain the Product under conditions of normal use and in accordance with the terms of the product literature, and other defects not related to materials or workmanship. This warranty does not apply to any Product that may have been repaired or altered by anyone other than Respironics.

Respironics disclaims all liability for economic loss, loss of profits, overhead, or indirect, consequential, special or incidental damages which may be claimed to arise from any sale or use of the Product. Some states do not allow the exclusion or limitation of incidental or consequential damages, so the above limitation or exclusion may not apply to you.

THIS WARRANTY IS GIVEN IN LIEU OF ALL OTHER EXPRESS WARRANTIES. IN ADDITION, ANY IMPLIED WARRANTY, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, IS SPECIFICALLY DISCLAIMED. SOME STATES DO NOT ALLOW DISCLAIMERS OF IMPLIED WARRANTIES, SO THE ABOVE LIMITATION MAY NOT APPLY TO YOU. THIS WARRANTY GIVES YOU SPECIFIC LEGAL RIGHTS, AND YOU MAY ALSO HAVE OTHER RIGHTS, WHICH VARY FROM STATE TO STATE.

To exercise your rights under this limited warranty, contact your local authorized Respironics, Inc. dealer or Respironics, Inc. at 1001 Murry Ridge Lane, Murrysville, Pennsylvania 15668, 1-800-345-6443 (USA and Canada only) or 1-724-387-4000.

Reorder Numbers

1030493	ComfortLite 2 w/ Headgear, S,M,L Pillows Cushion
1025111	ComfortLite 2 w/ Headgear, S,M,L Simple Cushion
1025127	ComfortLite 2 w/ Headgear, 4,5,6 Direct Seal Cushion
1025225	Sub-assembly w/ Headgear, No Cushions

Combo Packs

1030494	ComfortLite 2 Combo w/ Headgear, S,M Pillows & Simple Cushions
1030495	ComfortLite 2 Combo w/ Headgear, M,L Pillows & Simple Cushions
1025112	ComfortLite 2 Combo w/ Headgear, 4,5 Direct Seal, S,M Simple Cushions
1025113	ComfortLite 2 Combo w/ Headgear, 5,6 Direct Seal, M,L Simple Cushions

Replacement Parts

1025114	ComfortLite 2 Headgear strap only
1025117	ComfortLite 2 Headgear w/ Strap
1027999	Small Accessory Pouch
1032007	ComfortLite 2 Pillows Sizing Gauge (5 pk)
1031154	ComfortLite 2 Pillows Sizing Gauge (20 pk)
1018624	ComfortLite 2 Simple Cushion Sizing Gauge (20 pk)
1018665	ComfortLite 2 Direct Seal Cushion Sizing Gauge (20 pk)

Cushions (1 pk)

Pillows	Simple	Direct Seal	
1030502 - PETITE	1021835 - PETITE	1021802 - SIZE 1	1021816 - SIZE 5
1030503 - SMALL	1021830 - SMALL	1021806 - SIZE 2	1021817 - SIZE 6
1030504 - MEDIUM	1021823 - MEDIUM	1021807 - SIZE 3	
1030505 - LARGE	1021821 - LARGE	1021815 - SIZE 4	

Visit www.sleepapnea.com for a complete list of products and reorder numbers, or contact Customer Service at 1-800-345-6443 (US and Canada) or 1-724-387-4000 to obtain a product catalog (#1027825).